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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,780	11/17/2000	Helene Gras-Masse	1091/2 PCT/US	9478

7590 04/07/2005

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EXAMINER	
SALVOZA, M FRANCO G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,780	GRAS-MASSE ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *8,12-14,16,20 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,15,17-19,21-24* is/are rejected.

7)☒ Claim(s) *5 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

Applicant had reopened prosecution by filing a Request for Continued Examination. Applicant has withdrawn claims 8, 12 and 25 as reciting a non-elected invention.

Applicant has also canceled claims 13, 14, 16, and 20, though they have preserved the right to pursue claims 13, 14, 16 and 20 in continuing applications.

Claims 1-7, 9-11, 15, 17-19 and 21-24 are under consideration.

Claim Objections

Claim 5 is objected to because of the following informalities: it is grammatically incorrect, since the claim needs the preposition "to" to complete the prepositional phrase "according to." Appropriate correction is required.

Claim 22 is objected to because of the following informalities: it is grammatically incorrect, since the claim uses the language "wherein *the at* least one lipid unit." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 depends improperly on canceled claim 20. It is unclear what is intended by this phrasing. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9-10, 15, 17-19, 21-24 were rejected under 103(a) for being obvious over Stuhler et. al., Sastry et. al., and Sugimoto et. al. Claim 11 was rejected under 103(a) for being obvious over Stuhler et. al., Sastry et. al., and Sugimoto et. al. and further in view of Kramer et. al. Claim 18 was rejected under 103(a) for being obvious over Stuhler et. al., Sastry et. al., Sugimoto et. al., Kramer et. al. and further in view of Shapiro et. al.

In applicant's paper submitted October 27, 2004, applicant argues that Sastry contains no disclosure or suggestion of a composition comprising micelles wherein each micelle contains more than one first lipopeptide comprising at least one CTL antigenic determinant and at least one lipid unit and a second lipopeptide comprising at least one

T helper determinant and at least one lipid unit. Applicant further argues that the reference consistently points to a single peptide sequence as proof that the art teaches away from the use of micelles that use a plurality of peptides such as the applicant's invention.

Applicant's arguments are considered but are found unpersuasive. The plurality of peptides is certainly essential to applicant's invention. However, one of ordinary skill in the art would not assume from Sastry that the use of the micelles would be limited to one lipopeptide. Sastry teaches eliciting cell-mediated immunity with micelles comprising short HIV envelope ***peptides*** of gp160 with two palmitic residues attached in acetic acid. Therefore, Sastry does teach a composition comprising more than one lipopeptide. Although they are derived from a single gp160 protein from HIV, the peptides derived from it contain more than one CTL determinant. One of ordinary skill in the art would have had a reasonable expectation to prepare lipid micelle polymers containing either a mixture of peptides or at least more than one peptide. In addition, if anything, Sastry teaches the importance of the selection of each peptide, but does not necessarily preclude the use of more than one. Furthermore, one of ordinary skill in the art at the time the invention was made would have been motivated to present various portions of a protein in the form of peptides, as Sastry et al. do, to ensure that the immune system is uniformly presented with a complete set of epitopes from the antigenic peptide. Therefore, Sastry does not teach so narrowly away from applicant's invention, but instead the reference teaches within the scope of ordinary skill in the art.

Accordingly, claim 11, which is dependent on independent claim 1, is rejected for the same reasons that claim 1 is unpatentable in further view of Kramer. Furthermore, since a combination of the cited references lead to the claimed composition, the addition of the teachings of Shapiro et. al. meet the limitations of claim 18 drawn to a method according to claim 17 wherein the dispersing of the lipopeptides dissolved in acetic acid is confirmed by a two-dimensional nuclear magnetic resonance method.

There does not appear to be a defect in the Stuhler, Sastry, Sugimoto, Kramer and Shapiro combination of references cited in the 35 U.S.C. 103(a) rejection. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art for reasons of record, and the rejection of claims 1-7, 9-11, 15, 17-19, 21-24 are maintained under 103(a) for obviousness.

Conclusion

Applicant's amendment necessitated the ground(s) or rejection presented in the Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner, Art Unit 1648

JAMES HOUSEL 4/4/05
SUPERVISORY PATENT EXAMINER
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